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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michael Johnson

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11/14/2008

WILEY REIN LLP
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER

BERTRAM, ERIC D

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

11/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/668,876	Applicant(s) JOHNSON, MICHAEL	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 17 and 19-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 17 and 19-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8/14/2008 have been fully considered but they are not persuasive. The applicant argues that Winkler does not disclose an electrically conductive element on the exterior surface of the catheter. First of all, Winkler does show the electrode 45 flush with the exterior surface of the catheter, as shown in figure 4A. The fact that this exterior surface is indented from the rest of the exterior surface is irrelevant. Secondly, In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the electrode is not on the exterior surface of the catheter) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
2. The applicant further argues that the exposed wires 45 are not electrodes, relying on Winkler's disclosure that "[e]lectrically conductive wires have never proven to be entirely satisfactory as the electrodes since a functional electrode requires a much larger surface area than can be provided by a flexible wire." *Id.*, col. 1:32-35 (emphasis added). However, the fact that conductive wires may be less than entirely satisfactory as electrodes, does not mean they are not electrodes. An electrode is merely any electrical contact that allows current to flow in or out. Clearly, the exposed wires are electrodes by definition. Again, the fact they may be less efficient or less effective than other electrodes does not mean they are not electrodes.

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3. Regarding claim 16, the Examiner acknowledged in the previous Office Action that Winkler does not disclose electro-depositing a conductive, biocompatible material within a depression formed on the catheter tip. The inclusion of claim 16 under the 35 USC 102(b) rejection was inadvertent, and as such, that rejection has been withdrawn. However, the claim was also rejected under 35 USC 103(a). The Examiner still maintains that it would have been an obvious design choice to electro-deposit the electrically conductive material, as described below.

4. Regarding claim 32, the claim only requires that the remaining portion of the overmold adjacent to the electrode is "*generally smooth*" (emphasis added). It is the Examiner's position that the outer surface of the catheter will still be "generally smooth," especially since the depth of the removed portion cannot be greater than 0.02 inches (Col. 6, lines 15-22). Furthermore, the applicant admits that figure 1 shows a generally smooth finish. Therefore, the applicant must also consider figure 4D to show a generally smooth finish as well, since this shows the same thing as figure 1, only in greater detail. Figure 4D and Figure 4A show the same depression. If figure 4D is "generally smooth," then figure 4A should be as well.

5. Regarding the 35 USC 103(a) rejections of claims 16, 20, 24 and 28, the applicant merely relied on the arguments presented against Winkler, which have been addressed above.

6. The 35 USC 102(b) and 103(a) rejections of claims 16, 17 and 19-33 are still considered proper.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 16-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 7,234,225. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite the same invention, merely in different terms.

9. Claims 16-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 11/819,297. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite the same invention, merely in different terms.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 17, 19, 21-23, 25-27 and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Winkler (US 5,417,208). Winkler discloses a catheter 10 for use in a medical procedure with a catheter body 12 and a catheter tip 60 connected to the catheter body (see figure 1). As seen in figure 4A, Winkler discloses an arbitrarily-shaped electrode 45 that is originally overmolded by portion 20 of the catheter, but is exposed through and completely surrounded by the overmold 20 once a via 47 is made (Col. 6, lines 6-22). Furthermore, an energy delivery element 51 is operably coupled to the electrode (see figure 4B-4D and Col. 6, lines 51-68).

12. Regarding claims 17, 21-23, 25 and 26, Winkler discloses in figure 6 a lumen tube 44 and the jacket 20, the lumen tube nested within the jacket. Furthermore, figure 6 shows the electrode extending through the jacket, and the delivery element 51 is considered a wire formed on the exterior surface of the lumen tube, which is shown in figure 4D to run along the tube.

13. Regarding claim 19, Winkler discloses that the electrode is composed of stainless steel, which is a known biocompatible material (Col. 5, lines 5-7).

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14. Regarding claims 27, 29 and 30, it is the Examiner's position that the delivery element is inherently a "trace", and the trace 51 is surrounded by the body 20, as shown in figure 4D.

15. Regarding claims 31 and 32, figure 1 shows a plurality of arbitrarily exposed electrodes insulated from one another by the overmold. Furthermore, it is the Examiner's position that the catheter has a "generally" smooth finish.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 16, 20 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler. Winkler, as described above, discloses the applicant's basic invention with the exception of electrodepositing the electrodes and traces onto the catheter. However, it would have been an obvious matter of design choice to modify Winkler by electro-depositing the traces and electrodes onto the catheter since, upon reviewing the

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specification, the applicant has not disclosed that electro-depositing the traces and electrodes solves any stated problem or is for any particular purpose, and it appears that the catheter would perform equally well no matter how the electrodes or the traces have been attached to the catheter.

19. Regarding claim 20, the use of platinum and gold in medical devices as electrically conductive material is notoriously old and well known in the art, and their use in Winkler as a substitute for stainless steel would have been obvious to one of ordinary skill in the art and would have produced predictable results.

20. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler in view of Quackenbush (US 5,125,913). Winkler, as described above, discloses that applicant's basic invention, including a catheter comprising a tube along which wire is run. Winkler does not disclose, however, that the tube and wire are co-extruded.

Attention is directed to the secondary reference of Quackenbush, which discloses the use of co-extrusion when forming a medical catheter. Therefore, it would have been obvious to one of ordinary skill in that art at the time of the applicant's invention to modify the catheter of Winkler by co-extruding the tube and wire as suggested by Quackenbush because co-extrusion is a cheaper process since two steps can be completed in a single step.

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. D. B./
Examiner, Art Unit 3766

/Mark W Bockelman/
Primary Examiner, Art Unit 3766
November 9, 2008